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1 Claims

- 2
- 3 1. A method of monitoring the progression of
- 4 diabetes from a first timepoint to a later
- 5 timepoint, said method comprising the steps
- 6 providing a first biological sample
- 7 obtained at the first timepoint,
- 8 measuring the concentration of glycated
- 9 insulin in said biological sample,
- 10 providing a second biological sample
- 11 obtained at the later timepoint,
- 12 measuring the concentration of glycated
- 13 insulin in said second biological sample,
- 14 determining the difference in
- 15 concentration of glycated insulin between
- 16 the first and second biological samples,
- 17 wherein a lower concentration at the
- 18 second timepoint is indicative of
- 19 increased disease severity and/or loss of
- 20 control of blood glucose.
- 21
- 22 2. A method of early diagnosis of diabetes in an
- 23 individual, the method comprising the steps
- 24 providing a biological sample in which glucose
- 25 levels are within a normal range from said
- 26 individual,
- 27 measuring the concentration of glycated insulin
- 28 in the biological sample,
- 29 wherein the presence of glycated insulin at a
- 30 concentration greater than a predetermined minimum
- 31 is indicative of the presence of diabetes.
- 32

- 1 3. A method of predicting the onset of diabetes in
2 an individual, the method including the steps
3 of;
4 providing a biological sample from said
5 individual,
6 measuring the concentration of glycated insulin
7 in the biological sample,
8 wherein the presence of glycated insulin at a
9 concentration greater than a predetermined
10 minimum is indicative of predisposition to
11 diabetes.
12
- 13 4. The method according to claim 3, wherein the
14 concentration of glucose in the biological
15 sample is within the normal range.
16
- 17 5. The method according to claim 2 or claim 4
18 wherein the normal range of glucose is less than
19 11.1 mmol/l in a random plasma sample.
20
- 21 6. The method according to any one of claims 2 to 5
22 wherein said predetermined minimum concentration
23 is the concentration of glycated insulin
24 measured in a sample from the same individual at
25 an earlier timepoint.
26
- 27 7. The method according to any one of claims 2 to
28 6, wherein said predetermined minimum
29 concentration of glycated insulin in a non
30 fasted sample is at least 20 pmol/l.
31

- 1 8. A method as claimed in any preceding claim
2 wherein glycated insulin in the sample is
3 measured by means of radioimmunoassay (RIA).
4
- 5 9. Use of glycated insulin, as a predictive marker
6 for glucose intolerance and/or diabetes.
7
- 8 10. Use of glycated insulin as a predictive marker
9 for prediabetes or to predict the onset of
10 diabetes.
11
- 12 11. An *in vitro* assay method for detecting the
13 presence of glycated insulin in a biological
14 sample, in which glucose levels are normal, said
15 assay method comprising the steps:
16 providing a biological sample;
17 measuring the concentration of glycated insulin
18 in the biological sample;
19 wherein the presence of glycated insulin at a
20 concentration greater than a predetermined
21 minimum is indicative of diabetes or
22 predisposition to diabetes.
23
- 24 12. The method according to claim 11, wherein the
25 predetermined minimum is the concentration of
26 glycated insulin measured in a sample from the
27 same individual at an earlier timepoint.
28
- 29 13. The method according to claim 11 or claim 12
30 wherein the predetermined minimum concentration
31 in a non fasted sample is at least 20 pmol/l.
32

1 14. An assay kit for carrying out a method according
2 to any one of claims 1 to 8 or 11 to 13;
3 said kit comprising at least one antibody with
4 binding specificity to glycated insulin, means
5 to detect binding of the at least one antibody
6 to Glycated insulin, details of a concentration
7 range of Glycated insulin considered to be
8 elevated from normal levels, and instructions on
9 how the assay is to be performed and how the
10 results are to be interpreted..